THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CureVac SE, *et al*.,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 2:23-cv-0222 (JKW-DEM)
v.	)	
	)	
BioNTech SE, *et al*.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	
	)	
	)	
	)	

DEFENDANTS' PRETRIAL BRIEF

Defendants BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech") and Pfizer Inc. (collectively with BioNTech, "Defendants") respectfully submit this Pretrial Brief pursuant to Section XIII of ECF No. 240, identifying certain issues Defendants expect to arise at trial. This Pretrial Brief is intended to be a helpful guide for the Court to identify certain key issues that Defendants anticipate may arise; it is not intended to cover every issue or to limit the arguments or evidence Defendants expect to present at trial.

I. FACTUAL BACKGROUND

A. The Asserted Patents

Plaintiffs CureVac SE and CureVac Manufacturing GmbH (collectively, "Plaintiffs") assert 7 patents across 4 different patent families against Defendants (the "Asserted Patents"):

Reference Name	U.S. Patent No.	Issue Date	Asserted Claim(s)
Poly(A) patents	11,149,278	10/19/2021	15
	11,286,492	3/29/2022	6, 30
	11,345,920	5/31/2022	28
TFF patents	10,760,070	9/1/2020	7, 23
	11,667,910	6/6/2023	5, 13
G/C patent	11,135,312	10/5/2021	15
SARS patent	11,596,686	5/7/2023	14

B. The Accused Product

This case concerns Defendants' COVID-19 vaccine, COMIRNATY®. Defendant BioNTech designed and made COMIRNATY® as part of "Project Lightspeed," beginning in January 2020 by leveraging BioNTech's existing mRNA technology platforms developed through some two decades of scientific research and drug discovery. In March 2020, BioNTech

partnered with Defendant Pfizer to advance clinical testing, manufacturing, distribution, and regulatory approval of a COVID-19 vaccine. On July 13, 2020, Defendants announced that their vaccine candidate had received Fast Track designation from the U.S. Food and Drug Administration ("FDA"). On November 20, 2020, Pfizer, on behalf of Defendants, submitted an Emergency Use Authorization ("EUA") request to the FDA for administering Defendants' vaccine to people 16 years of age and older. On December 11, 2020, the FDA granted the EUA, and the COVID-19 vaccine was distributed immediately thereafter. Defendants' COMIRNATY® product was the first mRNA drug product, and the first COVID-19 vaccine, to receive full FDA approval.

This is not a case of copying by Defendants. The Accused Product, COMIRNATY®, was independently designed by BioNTech and includes critical components of BioNTech's platform technology, including, for example, BioNTech's inventive split poly(A) tail (referred to by BioNTech as the "A30L70" split poly(A) tail), for which BioNTech submitted a patent application (the "BioNTech Eberle Patent Application") on July 11, 2014—before Plaintiffs filed the applications for any of Plaintiffs' asserted Poly(A) patents discussed above. In fact, Plaintiffs did not obtain any of the Asserted Patents until after BioNTech had created COMIRNATY® and partnered with Pfizer for clinical development.

In short, Plaintiffs are attempting to use patents they obtained *after* BioNTech created the accused vaccine and partnered with Pfizer to profit off Defendants' independently designed and developed products.

In addition to BioNTech's own technology, BioNTech also licensed technology used in COMIRNATY®, including the lipid nanoparticle ("LNP") formulation invented by third-party Acuitas Therapeutics, Inc. ("Acuitas"). At an earlier stage of this case, Plaintiffs asserted 4

patents in the SARS patent's family that claimed Acuitas's invention of LNPs. Acuitas moved to intervene to assert ownership rights to the subject matter claimed in those patents, Magistrate Judge Miller recommended granting the intervention motion, and Plaintiffs then entered into a settlement agreement with Acuitas to avoid litigation of this issue. Following that settlement, Plaintiffs entered a stipulation with Defendants dismissing 3 of the 4 previously asserted SARS patents and disclaiming several claims of the remaining SARS patent. In the stipulation, Plaintiffs acknowledged Defendants' right to use the Acuitas LNPs and provided covenants with respect to the dismissed patents and disclaimed claims of the SARS patent. However, Plaintiffs continue to assert claim 14 of the SARS patent, alleging infringement based on the use of LNPs invented by Acuitas and which CureVac acknowledged Acuitas had the right to license, including for use in the accused COVID-19 vaccine.

II. DEFENDANTS' MOTIONS *IN LIMINE*

Defendants filed *Daubert* motions to exclude testimony from Plaintiffs' damages expert, Mr. Daniel McGavock, and from their TFF patent technical expert, Andrew Zydney, Ph.D., as well as 15 motions *in limine* objecting to various items Plaintiffs may plan to raise at trial. (*See* ECF Nos. 470-473, 478-482, 577-615, 646-648.) On February 14, 2025, Judge Miller granted Defendants' *Daubert* motion with respect to Dr. Zydney, ruling that CureVac could not assert, and Dr. Zydney could not opine at trial, that the phrase "TFF membrane cassette" in the TFF Patents should be construed to add a limitation that the TFF membrane cassettes are TFF membrane cassettes *with screens*. (ECF No. 753 at 8-16.)[1] Accordingly, Dr. Zydney will not be permitted to attempt to distinguish prior art or assert validity of the TFF patents based on claiming a TFF membrane cassette limited to one with a screen.

[1] Plaintiffs have filed Objections to Judge Miller's Opinion and Order (ECF Nos. 785-786), but fail to raise any grounds that would warrant reversing Judge Miller's Opinion and Order.

III. ISSUES AND DEFENSES

A. The Poly(A) Patents

In asserting their Poly(A) patents, Plaintiffs attempt to interfere with Defendants' use of BioNTech's own inventive technology in COMIRNATY®. Plaintiffs allege only indirect infringement by Defendants of Plaintiffs' Poly(A) patents. But Plaintiffs cannot prove that Defendants had the knowledge required for a finding of contributory infringement[2] because COMIRNATY® uses the A30L70 split Poly(A) tail developed by BioNTech, which indisputably predated Plaintiffs' purported invention.

In addition to noninfringement defenses, Defendants also assert that Plaintiffs' Poly(A) patents are invalid. BioNTech developed its inventive A30L70 poly(A) tail and filed the BioNTech Eberle Patent Application *before* Plaintiffs' applications for Plaintiffs' Poly(A) patents, thereby rendering Plaintiffs' Poly(A) patents anticipated and/or obvious. BioNTech's inventive poly(A) tail and the BioNTech Eberle Patent Application are prior art to, and disclose the subject matter claimed in, Plaintiffs' Poly(A) patents. Indeed, Plaintiffs' Poly(A) patents were granted because the U.S. Patent and Trademark Office ("PTO") examiner mistakenly believed that the BioNTech Eberle Patent Application was not prior art because Plaintiffs identified the wrong relevant date for the BioNTech Eberle Patent Application when disclosing it to the PTO.

[2] Plaintiffs initially alleged both induced infringement and contributory infringement of Plaintiffs' Poly(A) patents, but subsequently withdrew their induced infringement claim. In particular, Defendants moved for summary judgment of no indirect infringement (induced or contributory infringement) of Plaintiffs' Poly(A) patents. After Defendants replied in support of their summary judgment motion, and a week before oral argument, Plaintiffs sent the Court a notice that they were withdrawing their inducement of infringement claim under 35 U.S.C. § 271(b). (ECF No. 728.) Defendants will request that Plaintiffs' inducement claim be dismissed with prejudice, as was done with the provisional rights claim. (*See* ECF No. 518.)

The evidence will also establish that Plaintiffs' Poly(A) patents are invalid for lack of written description under pre-AIA 35 U.S.C. § 112, which requires that a patent specification convey to a person of ordinary skill in the art ("POSA") that the applicants possessed the claimed invention at the time of filing. (*See* ECF No. 506 at 8-12.) Plaintiffs fail to satisfy this standard, as they have tried to stretch the claims of Plaintiffs' Poly(A) patents beyond their description in the patents' specification in an effort to capture the BioNTech split poly(A) tail. In particular, the specification of Plaintiffs' Poly(A) patents shows that Plaintiffs' poly(A) tails used a specific structure that is very different from BioNTech's Accused Product – *i.e.*, a type of tail portion containing a histone stem-loop ("HSL") structure. [redacted] underscore that the specification for Plaintiffs' Poly(A) patents lacks sufficient written description because it fails to convey that the applicants possessed the claimed subject matter at the time of the application (and, indeed, they did not).

This behavior by Plaintiffs, combined with their continued assertion of these patents and other conduct in this case (including asserting patents claiming inventions of Acuitas), makes an award of attorneys' fees to Defendants appropriate under 35 U.S.C. § 285.

B. <u>The TFF Patents</u>

Regarding the TFF patents, Plaintiffs attempt to take credit for commercially available filters that they did not invent and that were publicly available and marketed for use with nucleic acids when the patents at issue were filed. The TFF patents are directed to using a tangential flow filtration ("TFF") cassette to filter RNA. These cassette filters were commercially sold *before* Plaintiffs filed the application for their patents, including expressly for filtering nucleic acids including RNA. These facts and others to be presented at trial establish the TFF patents are

invalid, for both anticipation and obviousness. The evidence will also establish non-infringement of the TFF patents by Defendants.

The evidence will further establish there were alternatives available that are not accused of infringement, which eliminates Plaintiffs' arguments for damages. [redacted]

C. The G/C Patent

The G/C patent issued in October 2021, more than 19 years after the application to which it claims priority was filed. This incredibly lengthy prosecution history reflects the PTO not allowing Plaintiffs broad claims directed to any increase in G/C content, and Plaintiffs' use of decades of prosecution to search for subject matter to claim, ultimately attempting to cover biotechnology that had evolved during the patent's prosecution. The original application was filed in 2002 and contained no actual research by the named inventors. For years, Plaintiffs watched the state of the art evolve, eventually trying to craft claims to capture later-arising technology. Specifically, the issued claims recite, *inter alia*, an mRNA that has at least a 7 percentage point increase in G/C content relative to an original coding sequence thereby producing a stabilized mRNA molecule, wherein the stabilized mRNA molecule enhances protein expression. However, the originally-filed patent does not disclose that a POSA can produce a stabilized mNRA molecule simply by increasing the G/C content of any mRNA over an original coding sequence by 7 percentage points. Indeed, the G/C patent does not present any research demonstrating this. Moreover, this limitation reciting a 7 percentage point G/C increase did not first appear in any pending patent claims until more than 7 years after the first patent application was filed. And even then, it was tied to a purported human cancer vaccine, and not a generalized statement *for all mRNA*. There is no dispute that the G/C patent's specification

includes no test data and does not disclose any stabilized mRNA that has a 7 percentage point G/C increase over the original coding sequence using the claimed method of G/C enrichment. The G/C patent is invalid for lack of written description under 35 U.S.C. § 112.

Defendants also assert the equitable defense of prosecution laches against enforcement of the G/C patent because the prosecution of that patent (1) included an unreasonable and unexplained delay by Plaintiffs, and (2) caused prejudice to Defendants, including intervening rights developed during the period of delay. While this equitable defense will be presented to the Court in the bench trial scheduled for April 15, 2025, some of the evidence presented during the jury trial will be relevant to that defense, including evidence regarding (1) the history and nature of the G/C patent (which bears on the element of Plaintiffs' unreasonable and unexplained delay) and (2) Defendants' efforts and investment in their own technology (which bears on the element of Defendants' prejudice and intervening rights).

Additionally, Plaintiffs will be unable to prove infringement by Defendants of the G/C patent. For example, Plaintiffs will be unable to show that the Accused Product increases G/C content compared to an original coding sequence by at least 7 percentage points to thereby produce a stabilized mRNA molecule. Plaintiffs also will be unable to show, *inter alia*, that G/C enrichment, including removal of a destabilizing sequence element ("DSE"), increases the stability of COMIRNATY®. Each of these points establishes non-infringement of the G/C patent.

Plaintiffs will also face significant hurdles in trying to prove that the tremendous success of COMIRNATY® has a nexus to the G/C patent and its limitation of an at least 7 percentage point increase in G/C content producing a stabilized mRNA molecule, as opposed to, for example, BioNTech's extensive technology embodied in the vaccine. The evidence will

establish that countless aspects of the mRNA technology unrelated to the G/C patent claims contribute to its performance and market success, which undermines Plaintiffs' arguments for secondary considerations of nonobviousness and damages.

D. The SARS Patent

When this case was filed, Plaintiffs asserted that the inventive aspect of the SARS patent was the use of LNPs with a COVID-19 vaccine. But the LNPs claimed in the SARS patent were the invention and property of Acuitas. Acuitas asserted inventorship of the Acuitas LNPs, co-ownership of these patents, and their right to license these patents to any of their customers, including Defendants. Plaintiffs mooted this claim by stipulating that they were not claiming that Acuitas's LNP technology was part of Plaintiffs' invention or that Defendants engaged in any wrongdoing or misconduct in using Acuitas's LNPs or components thereof. Without the right to claim Acuitas's LNPs as Plaintiffs' invention, the question then becomes what did Plaintiffs invent in the remaining asserted claim? The answer is that there is no invention remaining. Plaintiffs have retreated to pointing to a virus mutation *created by nature* (D614G). Not only did Plaintiffs not invent the virus mutation, they also did not discover it. An organization named GISAID published the sequence of the virus mutation, GISAID Sequence No. 406862, in a public database of which a POSA would have been aware, and it is therefore prior art, which was not before the PTO during examination. Other organizations published information drawing attention to that mutation. In sum, the virus mutation is not Plaintiffs' invention, nor is the basic idea of including a virus mutation in a vaccine targeting the virus. Moreover, at the time they filed the application for the SARS patent, Plaintiffs had not even created any vaccines targeting this virus mutation, further demonstrating that Plaintiffs did not invent the claimed virus mutation.

The evidence will further establish double patenting as to the SARS patent, including based on another patent in the SARS patent's family that was dismissed via the above-described stipulation. Plaintiffs, in fact, concede double patenting but rely on a "terminal disclaimer" they filed in the PTO as a putative cure. However, the terminal disclaimer became ineffective when Plaintiffs settled with Acuitas, separating the remaining SARS patent from the three other patents that were dismissed because of Acuitas's rights in those patents. 37 C.F.R. § 1.321(c)(3) (requiring that "any patent granted on that application . . . shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the judicially created double patenting").

Additionally, as the virus continued to evolve, Defendants worked more and more virus mutations into their vaccine. Plaintiffs will also face substantial hurdles proving that the one D614G mutation in the vaccine has any impact on the success of the Accused Product given the continuing evolution of the virus and numerous other mutations included in the vaccine (which are not the subject of the SARS patent), which undermines Plaintiffs' arguments for secondary considerations of nonobviousness and damages.

IV. CONCLUSION

Defendants welcome the opportunity to present the evidence to the jury and the Court, which will show that Defendants do not infringe the Asserted Patents and/or that the Asserted Patents are invalid. The evidence will further show that Plaintiffs' calculations and assertions of damages are flawed, improper, unapportioned, and unsupported.

Dated: February 24, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 24, 2025, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to all counsel of record.

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